

IN THE CLAIMS:

Claim 20 was previously cancelled. Claims 1, 14, 24, and 26 have been amended herein. All of the pending claims are presented below. This listing of claims will replace all prior versions and listings of claims in the application. Please enter these claims as amended.

Listing of the Claims:

1. (Currently amended) A pharmaceutical composition, wherein the pharmaceutical composition:
comprises a polytartrate polymer and at least one pharmaceutically active material;
releases pharmaceutically active material in a pulsatile manner when the composition is
administered to a human or animal; and
is in the form of a tablet prepared with a tablet press using a compression force of from 10 to
65 kN/cm²;
wherein the pharmaceutical composition does not comprise a barrier structure; ~~and~~
wherein the pulsatile manner includes an initial burst, a lag phase, and thereafter a second burst;
and
wherein the onset of the second burst is accompanied by dehiscence of the tablet.

2. (Previously Presented) The process according to claim 14, wherein the compression force in the tableting equipment is from 20 to 50 kN/cm².

3. (Previously Presented) The composition according to claim 1, wherein the polytartrate polymer forms degradation products that increase the pressure inside the pharmaceutical composition when the pharmaceutical composition is administered to a human or animal.

4. (Previously Presented) The pharmaceutical composition according to claim 3, wherein the degradation products comprise at least one compound selected from the group consisting of a C1 to C4 alcohol, aldehyde, ester, and acetone.

5. (Previously Presented) The pharmaceutical composition according to claim 4, wherein the degradation products comprise at least one compound selected from the group consisting of methanol, ethanol, propanol, isopropanol, and acetone.

6. (Previously Presented) The pharmaceutical composition according to claim 1, wherein the polytartrate polymer is a polycondensate of:

dimethyl tartrate, diethyl tartrate, diisopropyl tartrate, or one or more copolymers of at least two of dimethyl tartrate, diethyl tartrate, and diisopropyl tartrate; and one or more 2,3-O-alkylidenetartaric acid derivatives.

7. (Previously Presented) The pharmaceutical composition according to claim 6, wherein the polytartrate polymer is 2'3'-(1',4'-diethyl)-L-tartryl poly-(2,3-O-isopropylidene)-L-tartrate.

8. (Previously Presented) The pharmaceutical composition according to the claim 1, wherein the polytartrate polymer has a glass transition temperature that is greater than 40° C.

9. (Previously Presented) The pharmaceutical composition according to claim 1, wherein the pharmaceutically active material comprises at least one material selected from the group consisting of antigens, antibodies, and pharmaceutical substances.

10. (Previously Presented) The pharmaceutical composition according to claim 9, wherein the pharmaceutically active material is a GnRH agonist.

11. (Previously Presented) The pharmaceutical composition according to claim 10, wherein the pharmaceutically active material is buserelin.

12. (Previously Presented) The pharmaceutical composition according to claim 10, wherein the pharmaceutically active material is azagly nafarelin.

13. (Previously Presented) The pharmaceutical composition according to claim 1, wherein the tablet additionally comprises one or more pharmaceutically acceptable excipients or adjuvants.

14. (Currently amended) A process for preparing the pharmaceutical composition according to claim 1, wherein the process comprises:

a) mixing an effective amount of a pharmaceutically active material with a polytartrate polymer,

b) shaping the mixture with tableting equipment to form a compressed tablet by applying a compression force of from 10 to 65 kN/cm², and

c) determining a time length of the lag phase in release of the pharmaceutically active material from the compressed tablet;

wherein the compressed tablet releases the pharmaceutically active material in a pulsatile manner including an initial burst, the lag phase of a predetermined time, and thereafter a second burst when the pharmaceutical composition is administered to a human or animal; ~~and~~

wherein the compressed tablet does not comprise a barrier structure; and

wherein the onset of the second burst is accompanied by dehiscence of the tablet.

15. (Previously Presented) The process according to claim 14, wherein the pharmaceutically active material and the polytartrate polymer are mixed in a powdered form.

16. (Previously Presented) The process according to claim 14, wherein the mixture is sieved.

17. (Previously Presented) A method of administering a pulsatile pharmaceutically active material to a human or animal, wherein the method comprises administering the pharmaceutical composition of Claim 1 to the human or animal.

18. (Previously Presented) The method of Claim 17, wherein the method comprises administering the pharmaceutical composition of Claim 1 to a human.

19. (Previously Presented) A method of administering a pharmaceutically active material to a human or animal, wherein:

the method comprises administering the pharmaceutical composition of Claim 1 to the human or animal, and

a majority of the pharmaceutically active material is released in an initial burst and thereafter in a second burst.

20. (Canceled).

21. (Previously Presented) The method of Claim 17, wherein the method comprises administering the pharmaceutical composition of Claim 1 to a non-human animal.

22. (Previously Presented) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition is capable of releasing the pharmaceutically active material in a triphasic manner when the composition is administered to a human or animal.

23. (Previously Presented) The pharmaceutical composition of claim 22, wherein the triphasic matter comprises an initial burst phase, a lag phase, and thereafter in a second burst phase.

24. (Currently amended) A pharmaceutical composition, wherein the pharmaceutical composition:

consists essentially of

a polytartrate polymer,

at least one pharmaceutically active material, and

one or more pharmaceutically acceptable excipients or adjuvants;

wherein the pharmaceutical composition releases the pharmaceutically active material in a pulsatile manner including an initial burst, a lag phase, and thereafter a secondary burst when the pharmaceutical composition is orally administered to a human or animal; and

wherein the onset of the second burst is accompanied by dehiscence of the tablet.

25. (Previously Presented) The pharmaceutical composition of claim 24, wherein the pharmaceutical composition consists essentially of a polytartrate polymer and at least one pharmaceutically active material.

26. (Currently amended) A tablet for administering a pharmaceutically active material to a human or animal, said tablet prepared with tableting equipment using a compression force of from 10 to 65 kN/cm², which tablet does not comprise a barrier structure, the tablet comprising:

a polytartrate polymer that forms degradation products in the tablet that increase pressure inside the tablet, the degradation products comprising at least one compound selected from the group consisting of a C₁ to C₄ alcohol, aldehyde, ester, and acetone, and

at least one pharmaceutically active material,

wherein the tablet releases pharmaceutically active material therefrom in a pulsatile manner after administration to the human or animal; and

wherein the pulsatile manner includes an initial burst, a lag phase, and thereafter a second burst; and

wherein the onset of the second burst is accompanied by dehiscence of the tablet.